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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,197	12/16/2003	Frederic P. Field	D0188.70170US02	5833

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EXAMINER

FOSTER, MARLEE CHRISTINE

ART UNIT PAPER NUMBER

3731

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/737,197	Applicant(s) FIELD ET AL.	
	Examiner Marlee C. Foster	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11,13-20,39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11,13-20,39 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>07/08/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of apparatus claims 1-11 and 13-20 in the reply filed on 10 October 2006 is acknowledged. Claim 38 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Accordingly, claims 1-11, 13-20, and 39-40 are pending in the application.

Information Disclosure Statement

2. Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. See MPEP 609.05(b). Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

Art Unit: 3731

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-11 and 13-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of copending Application No. 10/352,6000. Although the conflicting claims are not identical, they are not patentably distinct from each other because the applications are claiming a suturing instrument comprising a means for driving deformable suture wire through a curved portion of a first channel with a wire advancing actuator, bending the suture wire in the curved portion such that, upon exiting the instrument, it follows a

Art Unit: 3731

curved trajectory in a curved surface in the first and second channel, cutting the suture wire to separate the trailing end from the remaining suture wire using the cutting bar and bending the leading and trailing ends inward with cutting bar towards the center of the wire.

This is a provisional obviousness-type double patenting rejection.

5. Claims 1-11 and 13-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 7,131,979. Although the conflicting claims are not identical, they are not patentably distinct from each other because the applications are claiming a suturing instrument comprising a means for driving deformable suture wire through a curved portion of a first channel, bending the suture wire in the curved portion such that, upon exiting the instrument, it follows a curved trajectory in a curved surface in the first and second channel to form a wire loop suture, receiving the leading end in a second channel, cutting the suture wire to separate the trailing end from the remaining suture wire using the cutting bar, and bending the leading and trailing ends inward with a cutting bar towards the center of the wire.

6. Claims 1-11 and 13-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,511,489. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent and the instant application are claiming the

Art Unit: 3731

following common subject matter a suturing instrument comprising a handle, a shaft, a channel adapted to hold a suture wire and bend it into a wire loop suture and a passageway intersecting the first and second island, adapted to guide the suture wire and support the cutting bar, which cuts the suture wire to a sharp point.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-7, 10, 16, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Caspari et al. (U.S. Patent 4,890,615). Caspari et al. disclose a suturing instrument comprising a handle (24 and 26), a shaft (36) having a proximal and distal end, a first and second island, a first channel (60) adapted to guide suture wire so as to form a loop upon exiting the opening, a second channel (66) adapted to receive suture wire after the suture wire has exited the opening, a wire drive (68) adapted to move the suture wire, and a cutter adapted to cut the suture wire so as to free the wire loop suture

Art Unit: 3731

from suture wire remaining in the instrument and bend each end of the wire loop suture around the first and second island. Regarding claims 2 and 3, the cutter (58) is further adapted to direct the wire loop suture away from the first and second channels in a lateral direction. The second channel has a curved surface adapted to contact the suture wire (figure 3). Regarding claim 4, the distal end has a recess adapted to receive the material to be sutured. The projections of the distal end are adapted to engage the material being sutured. The handles activate the wire cutter, and the cutter cuts the suture wire at an angle to form a point. Regarding claim 10, Caspari et al. disclose the material to be sutured is tissue (col. 2, line 57).

9. Claims 39 and 40 rejected under 35 U.S.C. 102(b) as being anticipated by Schulken et al. (U.S. Patent 5,499,990). Schulken et al. disclose a means for driving deformable suture wire through the curved portion of a first channel, a means for bending the suture wire in the curved portion such that upon exiting a distal end of the instrument so that a leading end of the wire follows a curved trajectory by moving the wire through a channel, a means for receiving the leading end in a second channel at the distal end as the suture wire returns (col. 5, lines 18-26), and a means for cutting the suture wire to separate the trailing end of the wire loop suture remaining in the suture instrument a severing mechanism (45). Schulken et al. additionally disclose a means for bending the two ends toward a center of the wire loop suture moving it through a guide channel (col. 8, lines 14-36).

Art Unit: 3731

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 8, 9, 11, 13, 14, 15, 17, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caspari et al. (U.S. Patent 4,890,615) in view of Schulken et al. (U.S. Patent 5,499,990). Caspari et al disclose a suturing instrument comprising a

Art Unit: 3731

handle, a shaft, a first and second channel, a wire drive, and a cutter. However Caspari et al. fail to disclose a cutting face, a relief face, and an ejection ramp face adapted to move the wire loop suture through a passageway and away from the first and second channels in a lateral direction. Caspari et al. additionally fail to teach a wire supply cartridge on the device.

14. Regarding claim 8, Schulken et al. teach a cutting face, a relief face, and an ejection ramp face adapted for directing the wire loop suture away from the first and second channels in a lateral direction. These different structures act to move the wire through a guide channel (col. 9, lines 12-57). Regarding claim 9, Schulken et al. teach an ejection push face to direction the wire loop suture away from the first and second channels. Schulken et al. teach this prevents kinking of the suture wire.

15. Regarding claim 13, the passageway (8, also 64 of figure 6b) of Schulken et al. is disposed between the islands of the device. Regarding claims 14 and 17, the device of Schulken et al. has a geometry of the first and second channels that aids in retaining the suture wire after it has been cut and bent (col. 3, lines 60-64 and see figure 3a).

16. Regarding claim 15, the wire drive advances a predetermined length of suture (col. 3, lines 7-15). Regarding claim 20, a wire supply cartridge is provided (col. 3, lines 17-20).

17. The features of Schulken et al. teach the geometry of using the instrument to effectively cut and bend wires while preventing kinking and allowing the application of several sutures during a procedure. Therefore, it would have been obvious to one of ordinary skill in the art to combine the devices of Caspari et al. and Schulken et al. to

Art Unit: 3731

improve the advancement by bending and cutting of the wire within the suturing instrument.

18. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caspari et al. (U.S. Patent 4,890,615) in view of Kortenbach et al. (U.S. Patent 5,814,054).

Caspari et al. disclose the device substantially as claimed, but fail to disclose a wire supply cartridge within the device. Kortenbach et al. teach a removable handle and needle on a suturing instrument (col.1, lines 54-65). This allows for accommodation of various sizes of needles on the instrument. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Caspari to accommodate different size needles and functions by allowing the shaft to be removable on the device.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Caspari et al. (U.S. Patent 5,522,820) discloses a device with similar features.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marlee C. Foster whose telephone number is (571) 272-5072. The examiner can normally be reached on Monday to Friday 8:00am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone

Art Unit: 3731

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



MCF



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11/27/02